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# **PATENT RIGHTS, ACCESS TO MEDICINES, AND THE JUSTICIABILITY OF THE RIGHT TO HEALTH IN KENYA, SOUTH AFRICA AND INDIA**

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## **Abstract**

This chapter examines how the national courts in three developing countries (Kenya, South Africa, and India) have addressed the tension between patent rights and the right to health in some of the cases litigated before them. National courts in developing countries are increasingly being confronted with disputes involving tensions between the enforcement of patent rights and the enjoyment of the right to health. As a result of the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights, developing countries that are members of the WTO are required to provide patent protection for pharmaceutical products. These patent rights however create a tension between the rights of pharmaceutical companies that own patents on essential drugs and the right to health of poor patients who cannot afford to pay for some of these patented drugs. The chapter is structured into three main parts. Part one examines the nature of the relationship between patent rights and the right to health while part two deals with the justiciability of the right to health in Kenya, South Africa, and India. Part three provides an analysis of how the national courts of these three developing countries have adjudicated some of the pharmaceutical patent cases involving tensions between the right to health and patent rights.

## **INTRODUCTION**

The human right to health is accorded recognition in a number of international legal instruments and in the basic law of several countries across the world. The recognition of the right to health in legal instruments, however, is not a guarantee that it is being enjoyed on an equal basis in every country in the world. There are several reasons why several people, particularly poor patients living in developing countries, do not enjoy the right to health. One contributory factor in this regard is the current global structure for the protection of intellectual property rights as embodied in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). Patent rights have a direct impact on the right to health, especially in developing countries where patented pharmaceutical products are usually priced beyond the reach of poor patients.

One of the international agreements that provides for the right to health is the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12(1) of the ICESCR mandates the states parties to the Covenant to 'recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'. In 2000, the UN

Committee on Economic, Social and Cultural Rights (UN CESCR) adopted General Comment No. 14 in an attempt to provide further definition for Article 12 of the ICESCR (UN CESCR 2000). Paragraph 12 of General Comment No. 14 is very relevant to the question of access to medicines. It enumerates four essential, interrelated components of the right to health: availability, accessibility, acceptability, and quality. In particular, it provides that essential drugs (as defined by the World Health Organization Action Programme on Essential Drugs) must be available in a country.

According to the World Health Organization (WHO), essential drugs are drugs that ‘satisfy the priority health care needs of the population’ and ‘are intended to be available within the context of functioning health systems at all times in adequate amounts ... and at a price the individual and the community can afford’ (WHO 2015). In addition, General Comment No. 14 states that health care services must be economically accessible to everyone, suggesting that the prices of essential drugs should not be so expensive as to be unaffordable for poor patients (UN CESCR 2000, para 12(b)). This makes access to essential medicines at an affordable price an integral component of the right to health (Hristova 2011, p. 356; UN Human Rights Council 2013).

States have an obligation to respect, protect and fulfil the right to health (UN CESCR 2000, para 33). The obligation to *respect* the right to health demands that states should not interfere directly or indirectly with the enjoyment of the right to health (Ibid). Essentially, the obligation to *respect* the right to health requires that states should, *inter alia*, ‘refrain from denying or limiting equal access for all persons ... to preventive, curative and palliative health services’ (Ibid para 34). The obligation to *protect* the right to health requires states to, *inter alia*, ‘adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties’ (Ibid para 35). The obligation to *fulfil* the right to health demands that states should, *inter alia*, ‘give sufficient recognition to the right to health in the national political and legal systems, preferably by way of legislative implementation, and to adopt a national health policy with a detailed plan for realizing the right to health’ (Ibid para 36).

The obligation of states to respect, protect and fulfil the right to health has implications for the design, implementation, interpretation and enforcement of their national patent laws. The obligation to *respect* the right to health requires that when designing, implementing, or interpreting patent laws, the various arms and organs of government (including the courts) should not adopt an approach that interferes directly or indirectly with the enjoyment of the right to health. In order to effectively *protect* the right to health, states should ensure that the patent rights owned by third parties such as pharmaceutical companies are not permitted to be exercised and enforced in a manner that makes it more difficult for poor citizens to have access to affordable generic drugs. The obligation to *fulfil* the right to health demands that, when designing or amending their national patent laws, states should not ignore or overlook the possible implications such legislative proposals can have on the realization of the right to health. States equally have core obligations with regard to the right to health. One of the core obligations of states is to ‘provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs’ (Ibid para 43(d)). It must be stressed that this core obligation is one from which no derogation is permissible (Ibid para 47).

The objective of this chapter is to examine how the national courts in three developing countries (Kenya, South Africa, and India) have addressed the tension between patent rights on pharmaceutical products and the right to health. The chapter is structured into three main parts. Part one examines the nature of the relationship between patent rights and the right to health while part two deals with the justiciability of the right to health in Kenya, South Africa, and India. Part three provides an analysis of how the national courts of these three developing countries have adjudicated some of the pharmaceutical patent cases involving tensions between the right to health and patent rights.

## **1. THE NATURE OF THE RELATIONSHIP BETWEEN PATENT RIGHTS AND THE RIGHT TO HEALTH**

There is a divergence of opinion with regard to how the relationship between patent rights and human rights should be conceptualized (Drahos 1999; Helfer 2003; Yu 2007a; Yu 2007b; Torremans 2008; Grosheide 2010; Helfer and Austin 2011; Gold 2013; Plomer 2013). In his review of the literature, Gold (2013, pp. 186-187) identifies three broad approaches to the conceptualization of the relationship between patent rights and human rights:

1. The ‘subjugation approach,’ which states that when patent rights and human rights conflict, human rights considerations should trump patent rights;
2. The ‘integrated approach,’ which views patents as a human right; and
3. The ‘coexistence approach,’ which asserts that patent law and human rights law are distinct but share a basic concern in defining the optimal amount of patent protection required to incentivize and practice socially useful innovation.

In his description of the ‘subjugation approach’, Helfer (2003, p. 48) notes that this approach ‘views human rights and intellectual property as being in fundamental conflict’ and it considers ‘strong intellectual property protection as undermining – and therefore as incompatible with – a broad spectrum of human rights obligations, especially in the area of economic, social, and cultural rights’. Helfer further notes that the ‘prescription that proponents of this approach advocate for resolving this conflict is to recognize the normative primacy of human rights law over intellectual property law in areas where specific treaty obligations conflict’ (Ibid). Plomer (2013, p. 151) suggests that this approach ‘might arguably be more accurately described as the “primacy of human rights” view’.

Gold (2013, p. 187-188) describes the ‘integrated approach’ as an approach that assimilates ‘patent rights into human rights analyses’ instead of ‘introducing human rights considerations into patent policy as advocated by some adherents of the subjugation approach’. The ‘integrated approach’ does not consider patents and human rights as distinct, rather it views ‘patents as part of human rights law’ (Ibid p. 188). However, as will be demonstrated below, advocates of the ‘integrated approach’ typically misconstrue the provisions of international human rights instruments such as Article 15(1)(c) of the ICESCR which provides for the protection of the moral and material interests of authors and inventors. They build their arguments on the false premise that provisions such as Article 15(1)(c) show that intellectual property rights (including patent rights) are human rights (Ibid p. 188).

Helfer (2003, p. 48) provides a description of the ‘coexistence approach’ as an approach that sees both human rights and intellectual property rights ‘as concerned with the same fundamental question: defining the appropriate scope of private monopoly power that gives authors and inventors a sufficient incentive to create and innovate, while ensuring that the consuming public has adequate access to the fruit of their efforts’. Helfer (Ibid) further notes that this approach ‘views human rights law and intellectual property law as essentially compatible, although often disagreeing over where to strike the balance between incentives on the one hand and access on the other’.

Before identifying the correct one among the three approaches, it is essential to first determine the status of intellectual property rights (including patent rights) under international human rights law. Article 15(1)(c) of the ICESCR recognizes the right of everyone to ‘benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author’. A similar provision is also contained in Article 27(2) of the Universal Declaration of Human Rights (UDHR). Article 27(2) of the UDHR provides that ‘Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author’. At first reading, these two provisions appear to equate intellectual property rights (IPRs) with other types of human rights and this has led some authors such as Millum (2008) and Marks (2009) to conclude that they provide a human rights basis for patent rights and other forms of IPRs.

However, the CESCR, in its General Comment No. 17, has made it clear that human rights and IPRs are not on the same level, and it will be erroneous to rely on Article 15(1)(c) to equate intellectual property rights with human rights (UN CESCR 2005, paras 1 & 3). According to the CESCR, Article 15(1)(c) solely ‘safeguards the personal link between authors and their creations ... as well as their basic material interests which are necessary to enable authors to enjoy an adequate standard of living’ while ‘intellectual property regimes primarily protect business and corporate interests and investments’ (Ibid para 2). In essence, the human right contained in Article 15(1)(c) is not coterminous with intellectual property rights. The approach adopted by the CESCR is equally supported by the drafting history of both Article 27(2) of the UDHR and Article 15(1)(c) of the ICESCR. It has been noted that the provisions were included in both instruments after considerable debates and controversy (Yu 2007a, p. 1073). According to Chapman (2001, p. 13), the drafting history of both the UDHR and ICESCR supports ‘relatively weak claims of intellectual property as a human right’.

Strictly speaking, the human right contained in both Article 15(1)(c) of the ICESCR and Article 27(2) of the UDHR is a right to the protection of the ‘moral and material interests’ of authors and inventors in their creative works. This right is separate from, and should never be confused with, intellectual property rights. The CESCR, in General Comment No. 17, stresses the point that the protection of the moral and material interests of authors and inventors does not necessarily coincide with what is currently regarded as intellectual property right in national laws and international agreements (UN CESCR 2005, para 2). While the right to the protection of the moral interests and material interests of authors and inventors in their creative works is a fundamental entitlement, intellectual property rights are not fundamental entitlements as they can be limited, traded, amended or even forfeited (Ibid).

With regard to the scope of the right to the protection of the *moral* interests of authors and inventors in their works, the CESCR notes that it includes ‘the right of authors to be recognized as the creators of their scientific, literary and artistic productions and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, such productions, which would be prejudicial to their honour and reputation’ (Ibid para 13). In other words, the right to the protection of the *moral* interests of authors and inventors is akin to the protection of moral rights contained in the copyright laws of countries such as Germany and France (Yu 2007a, pp. 1081-1082). The moral rights of authors should however not be confused with copyright (Drahos 1998, pp.13-14). One can thus infer from this that moral rights (as distinct from copyright) enjoy the status of human rights.

In distinguishing between the ‘moral interests’ of authors and inventors and the ‘material interests’ of authors and inventors, the CESCR in General Comment No. 17 notes that ‘Unlike other human rights, the material interests of authors are not directly linked to the personality of the creator, but contribute to the enjoyment of the right to an adequate standard of living’ (UN CESCR 2005, para 15). In other words, while the protection of the *moral interests* in intellectual creations deal with the personal connection between creators and their creations, the protection of the *material interests* in intellectual creations deal with the pecuniary connection between creators and their creations.

In an effort to distinguish between the protection of *material interests* on the one hand and the protection of intellectual property rights on the other hand, the CESCR notes that ‘the purpose of enabling authors to enjoy an adequate standard of living can also be achieved through one-time payments or by vesting an author, for a limited period of time, with the exclusive right to exploit his scientific, literary or artistic production’ (Ibid para 16). In other words, it is not mandatory to grant patent rights or copyright in order to protect the *material interests* of intellectual workers. The right of intellectual creators to an adequate standard of living, i.e. their *material interests*, can equally be protected through other means such as one-time payments, prizes, or monetary awards (Yu 2007a, p. 1089).

The CESCR admits that Article 15(1)(c) of the ICESCR does not specify the method or procedure for the protection of the *moral* and *material* interests of authors and inventors (UN CESCR 2005, para 10). Nevertheless, the CESCR notes that the protection under Article 15(1)(c) ‘need not necessarily reflect the level and means of protection found in present copyright, patent and other intellectual property regimes, as long as the protection available is suited to secure for authors the moral and material interests resulting from their productions’ (Ibid).

One other factor that distinguishes the protection of *moral* and *material* interests from the protection of intellectual property rights is the fact that the former, being human rights, are inalienable rights unlike intellectual property rights. As the CESCR points out, ‘intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While under most intellectual property systems, intellectual property rights, often with the exception of moral rights, may be allocated, limited in time and scope, amended and even forfeited, human rights [such as the moral and material interests of authors and inventors] are timeless expressions of fundamental entitlements of the human person’ (Ibid para 2).

The analysis provided above on the real meaning of the phrase ‘moral and material interests’ should be enough to dispel any notion that patent rights or any other forms of intellectual property rights are human rights as canvassed by proponents of the ‘integrated approach’. Furthermore, in relation to the human rights status of intellectual property rights, it is also important to note the decision of the Constitutional Court of South Africa in *Re Certification of the Constitution of the Republic of South Africa, 1996*, where with regard to the objection lodged against the failure of the new text of the South African Constitution to recognize a right to intellectual property based on the grounds that it was a ‘universally accepted fundamental right,’ the court held that the recognition of a right to intellectual property ‘can not be characterised as a trend which is universally accepted’ (*Re Certification*, para 75).

With regard to the ‘coexistence approach’, Gold (2013, p. 189) provides a very good critique thus:

...while proponents of the coexistence approach view human rights law and patent protection as essentially compatible in theory, disagreement often arises in practice over exactly where to strike the balance between incentives for innovation on the one hand and access on the other ... little exists by way of concrete examples of just how this “coexistence” plays out in practice. At best, the coexistence asserted by the proponents of this theory is more properly viewed as a *need* for coexistence, a need that recognises that neither intellectual property rights nor human rights are likely to disappear as concepts or institutions anytime soon.

In practice, it is quite difficult to foresee how human rights and intellectual property rights (including patent rights) can coexist in all aspects. There are aspects of patent rights, particularly patent rights on pharmaceutical products and processes, that negatively impact on the human right to health and when such conflicts occur, a practical choice has to be made between patent rights or human rights. More importantly, any notion that patent rights and human rights can ‘peacefully coexist’ is swiftly dispelled by the recent trend of incorporating TRIPS-plus standards into the bilateral and plurilateral free trade agreements negotiated (or currently being negotiated) between developed and developing countries outside the multilateral framework provided by the World Trade Organization (Sell 2007, p. 59). These TRIPS-plus standards can exacerbate the negative impact that patent rights have on the enjoyment of the right to health in developing countries.

The typical TRIPS-plus standards that are included in these bilateral and plurilateral free trade agreements include: the extension of patent terms to compensate for delays in the examination of patent applications or in obtaining marketing approval for a drug; patent linkage requirements that prevent the grant of marketing approval to producers of generic drugs when there is an existing patent on the brand name drug; the grant of patents on new forms or new uses of known drugs; periods of exclusivity for clinical test data; and border enforcement measures that permit customs authorities to seize goods suspected to have infringed patent rights (Correa and Matthews 2011, p. 21). These TRIPS-plus standards can limit the ability of a country to use the flexibilities in the TRIPS Agreement, delay the production of cheaper generic drugs, and consequently hinder access to affordable drugs (Ibid). There is therefore no better time than now for developing countries to insist on the primacy of human rights obligations.

The 'subjugation approach' therefore appears to be the preferable way to conceptualize the relationship between patent rights and human rights. Properly construed, the 'subjugation approach' does not suggest that patent rights should be discarded or abolished. It rather recognizes the essential distinction between the fundamental nature of human rights and the regulatory nature of patent rights. The intellectual property system (including the patent system) is best construed, according to Shubha Ghosh, as a system of rights and obligations that regulates creative activity (Ghosh 2008, p. 106).

Thus, if patent rights are not human rights under international human rights law, there is no justifiable reason why a country should allow its patent system to trump the enjoyment of the human right to health. This does not necessarily mean that patent rights should no longer be protected, but it means that states should not permit patent rights to be exercised in ways that impede the enjoyment of the human right to health. Patent rights should be made to serve the interests protected by human rights (Draho 1999, p. 367).

## **2. THE RIGHT TO HEALTH IN KENYA, SOUTH AFRICA AND INDIA**

### **2.1 Kenya and South Africa**

The jurisprudence on the right to health in South Africa is more robust than that of Kenya. This can be explained by the fact that the right to health was introduced into the South African Constitution in 1996, while it was only recently introduced into the Kenyan Constitution in 2010. Nevertheless, the right to health is a justiciable right in Kenya pursuant to Article 43(1)(a) of the Kenyan Constitution of 2010 which provides that everyone has the right to 'the highest attainable standard of health, which includes the right to health care services, including reproductive health care'. Thus, Kenyans can institute legal proceedings to challenge any governmental action (including legislative enactments on patent rights and other IPRs) that potentially or actually infringes on their right to health.

Section 27(1)(a) of the South African Constitution of 1996 provides that everyone has the right to have access to 'health care services, including reproductive health care'. Section 27(2) further mandates the South African government to take 'reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights'. Section 27(3) provides that no one may be refused emergency medical treatment. The South African Constitutional Court has, in a line of cases, made pronouncements on the meaning and effect of these provisions on the right to health.

In *Soobramoney v. Minister of Health*, the South African Constitutional Court held that the appellant's demand to receive dialysis treatment at a state hospital must be determined in accordance with sections 27(1) & (2) which provides for access to health care services provided by the state 'within its available resources' (*Soobramoney*, 1997, para 22). According to the court (*Ibid* para 29),

The provincial administration which is responsible for health services in KwaZulu-Natal has to make decisions about the funding that should be made available for health care and how such funds should be spent. These choices involve difficult decisions to be taken at the political level in fixing the health budget, and at the



functional level in deciding upon the priorities to be met. A court will be slow to interfere with rational decisions taken in good faith by the political organs and medical authorities whose responsibility it is to deal with such matters.

The court in this case adopted what Ferraz calls the ‘reasonableness approach’ and, as Ferraz points out, the court confined its role ‘to an assessment of the rationality and good faith of the decisions taken at the political and technical branches of the state’ (Ferraz 2013, p. 385).

The ‘reasonableness approach’ to the right to access to health care was also followed in the decision of the same court in the latter case of *Minister of Health & Ors v. Treatment Action Campaign & Ors (No.2)* (*Minister of Health*, 2002). There are however crucial differences between the facts of *Soobramoney* and the *Treatment Action Campaign (TAC) case*. In the *TAC case*, TAC (an NGO involved in HIV/AIDS Advocacy) challenged the restrictions imposed by the South African government on the availability of nevirapine (a drug that can be used to prevent mother-to-child transmission of HIV) in the public health sector (Ibid para 4). The government had confined the administration of the drug to research and training sites. TAC contended that these restrictions were unreasonable vis-à-vis the provisions of the Constitution (Ibid). According to TAC, ‘the measures adopted by government to provide access to health care services to HIV-positive pregnant women were deficient in two material respects: first, because they prohibited the administration of nevirapine at public hospitals and clinics outside the research and training sites; and second, because they failed to implement a comprehensive programme for the prevention of mother-to-child transmission of HIV’ (Ibid para 44).

One of the key issues the court had to consider was whether, in the light of provisions such as section 27 of the Constitution, the government was constitutionally obliged and had to be ordered to plan and implement an effective, comprehensive and progressive programme for the prevention of mother-to-child transmission of HIV throughout the country (Ibid para 5). The court in applying its ‘reasonableness approach’ held that the ‘policy of confining nevirapine to research and training sites fails to address the needs of mothers and their newborn children who do not have access to these sites. It fails to distinguish between the evaluation of programmes for reducing mother-to-child transmission and the need to provide access to health care required by those who do not have access to the sites’ (Ibid para 67). Unlike its attitude towards government’s policy in *Soobramoney*, in this case, the court was willing to question the government’s policy with regard to the administration of nevirapine and it held that ‘the policy of government in so far as it confines the use of nevirapine to hospitals and clinics which are research and training sites constitutes a breach of the state’s obligations under section 27(2) read with section 27(1)(a) of the Constitution’ (Ibid para 80). The policy was held to be unreasonable. According to the court, ‘a policy of waiting for a protracted period before taking a decision on the use of nevirapine beyond the research and training sites is also not reasonable within the meaning of section 27(2) of the Constitution’ (Ibid para 81).

The court ordered the government to, *inter alia*, remove without delay, ‘the restrictions that prevent nevirapine from being made available for the purpose of reducing the risk of mother-to-child transmission of HIV at public hospitals and clinics that are not research and training sites’ (Ibid para 135(3)(a)). The implication of the *TAC* case is that, even though the South African Constitutional Court prefers to adopt a ‘reasonableness approach’ in its evaluation of

government policies that affect socio-economic rights and despite the fact that the court equally respects the doctrine of separation of powers, where the government adopts a policy that is unreasonable and inconsistent with the provisions of the Constitution, the court can actually give an order that has an impact on policy making.

It should also be noted that in the *TAC* case, the government's policies with regard to the administration of nevirapine was not based on resource constraints like in the *Soobramoney* case. As Ferraz notes, the 'cost of providing the drug was virtually none, given a pledge by the pharmaceutical suppliers to give it for free' (Ferraz 2013, p. 388). Even the court acknowledged the fact that the 'cost of nevirapine for preventing mother-to-child transmission is not an issue in the present proceedings' and that it was 'admittedly within the resources of the state' (Constitutional Court of South Africa 2002, para 71). The government policies on nevirapine were based on what Ferraz (2013, p. 388) calls 'dubious (not to say completely ungrounded) assertions that the drug in question (Nevirapine) was not scientifically proven to work'.

In *Minister of Health v. New Clicks*, (*Minister of Health*, 2005), the South African Constitutional Court held that the right to health also includes the right to have access to affordable medicines and that the state has an obligation to 'promote access to medicines that are affordable' (Ibid para 514). According to Sachs J. in this case, 'preventing excessive profit-taking from the manufacturing, distribution and sale of medicines is more than an option for government. It is a constitutional obligation flowing from its duties under section 27(2)' (Ibid para 659). In the same case, Moseneke J. (Ibid para 706) stated that,

It seems self-evident that there can be no adequate access to medicines if they are not within one's means. Prohibitive pricing of medicine ... would in effect equate to a denial of the right of access to health care. Equally true is that the state bears the obligation to everyone to facilitate equity in the access to essential drugs which in turn affect the quality of care.

A combined reading of section 27 of the South African Constitution and the decisions in *Soobramoney*, *TAC*, and *New Clicks* leads one to conclude that the right to health care in South Africa, which includes the right to have access to affordable medicines, imposes an obligation on the government to facilitate access to affordable medicines through the adoption of reasonable measures though this obligation can only be fulfilled within the limits of available resources. Furthermore, where the government adopts a policy that is inconsistent with the Constitution and which also violates the right to health, the court can demand that the government should change its policy.

## **2.2 India**

The Indian Constitution, which came into force in 1950, incorporates civil and political rights as fundamental rights in Part III of the Constitution while socio-economic rights are contained in Part IV of the Constitution which deals with the Directive Principles of State Policy. In relation to health, Article 39(e), contained in Part IV of the Constitution, provides that the state shall, in particular, direct its policy towards securing 'that the health and strength of workers, men and women, and the tender age of children are not abused'. Another provision in Part IV of the Constitution that touches on health is Article 41 which provides

*inter alia* that the state ‘shall, within the limits of its economic capacity and development, make effective provision for securing the right to ... public assistance in cases of ... sickness and disablement’. Furthermore, Article 47, also contained in Part IV of the Constitution, provides *inter alia* that the state ‘shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties’.

However, the provisions of Part IV of the Indian Constitution are non-justiciable. According to Article 37 of the Constitution, the provisions of Part IV of the Constitution ‘shall not be enforceable by any court’ though ‘the principles therein laid are nevertheless fundamental in the governance of the country’ and the state has the duty ‘to apply these principle in making laws’. Initially, the Indian Supreme Court adopted a strict approach towards the interpretation of this prohibition against the justiciability of the Directive Principles of State Policy. As Dhanda (2013, p. 406) points out,

In the early years, this prohibition of justiciability was strictly interpreted by the Supreme Court. Thus, the Court ruled that legislation was required for the implementation of the Directives. The [Directive Principles of State Policy] without more did not create a justiciable right in favour of individuals. Consequently, courts could not compel the state to carry out any of the [Directive Principles of State Policy]. Further, due to the prohibition on justiciability, no law could be declared void on the ground that it infringed the [Directive Principles of State Policy].

In subsequent years, however, the Indian Supreme Court began to adopt an ‘expanded reading’ of the justiciable provisions on civil and political rights and they ‘started to pronounce upon matters of health which were by the text of the Constitution included in the [Directive Principles of State Policy]’ (Dhanda 2013, p. 406). Essentially, the court found a way of ‘settling the contours of the right to health’ through the adoption of an expansive reading of the fundamental right to life contained in Article 21 of the Indian Constitution (Ibid). According to Article 21 of the Indian Constitution, ‘No person shall be deprived of his life or personal liberty except according to procedure established by law’.

Dhanda notes that the Indian Supreme Court ‘started with a very formal and legalistic interpretation’ of the right to life by ruling ‘that the deprivation of life and liberty was permissible provided it was done by a duly enacted parliamentary legislation’ (Ibid). The Supreme Court moved progressively from this formal and legalistic interpretation and it started to expand the ambit of the right to life by first enhancing ‘the fairness requirements of the right to life and liberty depriving procedure’ and then the court later pronounced on ‘the quality of life guaranteed by the Constitution’ (Ibid). The court ruled that the right to life ‘was not a right to bare physical existence but a right to a full and meaningful life. And a full and meaningful life includes the right to health within its purview’ (Ibid pp. 406-407). Some of the cases where the Indian Supreme Court has made pronouncements on the right to health are examined below.

In *Consumer Education & Research Centre and others v. Union of India and others*, the Indian Supreme Court held that the ‘expression “life” assured in Art. 21 of the Constitution does not connote mere animal existence or continued drudgery through life. It has a much wider meaning which includes right to livelihood, better standard of life, hygienic conditions in [the] work place and leisure’ (*Consumer Education & Research Centre*, 1995, para 24). In

the same case, the Supreme Court held that ‘the right to health and medical care is a fundamental right under Article 21’ (Ibid para 26).

In *Paschim Banga Khet Samity v. State of West Bengal*, (*Paschim Banga Khet Samity*, 1996, para 9), which involved the failure of government medical hospitals to provide timely emergency medical treatment to an individual who fell off a train and who suffered serious head injuries and brain haemorrhage, the Indian Supreme Court held that,

Article 21 imposes an obligation on the State to safeguard the right to life of every person. Preservation of human life is thus of paramount importance. The Government hospitals run by the State and the Medical Officers employed therein are duty bound to extend medical assistance for preserving human life. Failure on the part of a Government hospital to provide timely medical treatment to a person in need of such treatment results in [a] violation of his right to life guaranteed under Article 21.

The court further noted that the limitation of financial resources cannot justify the failure of the state to discharge its constitutional obligations with regard to the provision of adequate medical services (Ibid para 16). However, arguments relating to the limitation of financial resources in the context of the right to health and the provision of medical facilities by the state are not entirely foreclosed by the Indian Supreme Court. Where, due to the limitation of financial resources, the government has adopted a particular policy with regard to the provision of medical services, the Indian Supreme Court assesses the particular policy by adopting an approach akin to the ‘reasonableness approach’ adopted by the South African Constitutional Court in the *Soobramoney* case.

For instance, in *State of Punjab and others v. Ram Lubhaya Bagga*, the Indian Supreme Court had to determine whether the State of Punjab was justified in adopting a policy of not reimbursing an employee for his full medical expenses if such expenses were incurred in any hospital in India that was not a government-owned hospital in Punjab. In this case, the Supreme Court (*State of Punjab*, 1998) held that,

[S]o far as questioning the validity of governmental policy is concerned, in our view it is not normally within the domain of any court, to weigh the pros and cons of the policy or to scrutinize it and test the degree of its beneficial or equitable disposition for the purpose of varying or modifying it, based on however sound and good reasoning, except where it is arbitrary or violative of any constitutional, statutory or any other provision of law. When Government forms its policy, it is based on [a] number of circumstances ... including constraints based on its resources ... it would be dangerous if [the] court is asked to test the utility, beneficial effect of the policy or its appraisal based on facts set out on affidavits. The Court would dissuade itself from entering into this realm which belongs to the executive. It is within this matrix that it is to be seen whether the new policy violates Article 21 when it restricts reimbursement on account of ... financial constraints.

In other words, once the government has already adopted a policy with regard to the provision of a medical facility, unless the said policy is arbitrary or unreasonable, the court will not interfere in accordance with the doctrine of separation of powers. The implication of this is that the government cannot rely on the argument that it has financial constraints to justify its failure to provide a medical facility. As the court held in the *Samity case*, the state

cannot avoid its obligation on account of financial constraints. The state has to take steps to establish a policy with regard to the provision of medical facilities and limited financial resources will not excuse the government's failure to establish a policy in this regard. But once the government has adopted a particular policy with regard to the provision of a medical facility, the court will only interfere where that policy is unreasonable or violative of the Constitution.

Thus in the *Lubhaya Bagga* case, the court held that, 'the State can neither urge nor say that it has no obligation to provide [a] medical facility. If that were so it would be ex facie violative of Article 21' (Ibid). The court then noted that under the policy adopted by the State of Punjab, 'medical facility continues to be given and ... an employee is given [the] free choice to get treatment in any private hospital in India but the amount of payment towards reimbursement is regulated' (Ibid). The court held that this policy was not in violation of Articles 21 or 47 of the Constitution (Ibid). The approach adopted by the court in the *Lubhaya Bagga* case was followed in the latter case of *Confederation of Ex-Servicemen Associations and others v. Union of India and others* (Supreme Court of India 2006).

In 2014, in the case of *Mohd. Ahmed (Minor) v. Union of India and others*, the Delhi High Court made some landmark pronouncements on the right to health in the context of access to medicines as it affects a patient suffering from a rare disease (*Mohd. Ahmed*, 2014). The central issue before the court was whether a child born to poor parents and who is suffering from Gaucher's disease (a chronic and rare disease) is entitled to free medical treatment especially when the treatment for the disease is known, the prognosis is good, and there is every likelihood that the child can lead a normal life (Ibid para 1).

It was argued on behalf of the child that, since the drugs needed for the treatment of the child is available in India, both the Central Government and the Government of Delhi had an obligation under Article 21 of the Constitution to provide free treatment to the child and other patients in the same situation (Ibid para 11). The child's counsel argued that the government could not raise the plea of financial constraint (Ibid para 14). The plea of financial constraint however formed the kernel of the submissions made by the Central Government and the Government of Delhi. They contended that because of their limited resources they are unable to fund the treatment of the child as the disease is a lifelong one and the condition of the child is chronic (Ibid para 27).

Anand Grover, the former UN Special Rapporteur on the Right to Health, equally made some legal submissions in this case. Grover argued that, as India had signed and ratified the International Covenant on Economic, Social and Cultural Rights (ICESCR), India is duty bound to fulfil its international legal obligations (Ibid para 34). According to Grover (Ibid para 35),

States are required to adopt and implement a public health strategy and plan of action that reflects the epidemiological burden of disease that not only addresses major disease burdens but also the health concerns of the whole population. Therefore ... even if a small percentage of the population had a life-threatening condition there should be [a] public health strategy and plan to address their treatment needs. In other words, the Government can be directed to have a plan in place to make medicines available for rare diseases, like Gaucher disease etc.

Grover's argument brings into focus the central problem with the government's argument in this case. Essentially, the Indian government had failed to put in place a policy or adopt a public health strategy to provide medicines to those suffering from rare diseases such as Gaucher's disease. This is a violation of the government's obligation with regard to the right to health. It is true that the government has limited resources, but as the Indian Supreme Court held in the *Samity* case, the state cannot avoid its constitutional obligation with regard to the right to health on account of financial constraints. Even in the *Lubhaya Bagga* case where the Indian Supreme Court recognized the fact that the financial resources of the state are not unlimited, the court still made it clear that the failure to adopt a policy with regard to the provision of a medical facility is *ex facie* violative of the Constitution.

In this case, neither the Central Government nor the Delhi Government had adopted any policy or public health strategy for the provision of drugs to those suffering from rare diseases. As the Delhi High Court pointed out, 'Unfortunately, the Government of India does not have any policy measure in place to address rare diseases, particularly those of a chronic nature. All the Central and State schemes at the highest provide for a one-time grant for life-saving procedures and do not contemplate continuous financial assistance for a chronic disease such as [Gaucher's disease], which involves lifelong expenditure' (Ibid para 42). The court however stated that, in accordance with the doctrine of separation of powers, it could not direct parliament to enact a legislation on the right to public health or with regard to rare diseases or orphan drugs, even though this may be eminently desirable (Ibid para 44). According to the court, as the 'formulation of a policy is within the exclusive domain of the Executive,' it will refrain from issuing directives for the formulation of a policy (Ibid para 45).

In its decision in this case, the court referred to the UN CESCR's General Comment No. 14 on the right to health. The court quoted paragraph 43(d) of General Comment No. 14 which states that one of the core obligations with regard to the right to health (from which no derogation is permissible) is the provision of essential drugs. Furthermore, the court quoted paragraph 52 of General Comment No. 14 which provides that a state violates its obligation to fulfil the right to health when it fails to, *inter alia*, 'adopt or implement a national health policy designed to ensure the right to health for everyone'. The court admitted that the state does not have unlimited financial resources. Nevertheless, the court held that 'no Government can say that it will not treat patients with chronic and rare diseases due to financial constraint[s]' (Ibid para 64). The court adopted the view that 'core obligations under the right to health are non-derogable' and that though 'this minimum core is not easy to define,' it 'includes at least the minimum decencies of life consistent with human dignity' (Ibid para 67).

Invariably, the court came to the conclusion that the state has an obligation to provide access to medicines, including medicines for rare diseases. According to the court (Ibid paras 68-69), '

Article 21 of the Constitution clearly imposes a duty on the Government to take whatever steps are necessary to ensure that everyone has access to health facilities, goods and services, so that they can enjoy, as soon as possible, the highest attainable standard of physical and mental health ... Government must at the bare minimum ensure that individuals have access to essential medicines even for rare diseases like

enzyme replacement for Gaucher disease ... Government cannot cite financial crunch as a reason not to fulfil its obligation to ensure access to medicines or to adopt a plan of action to treat rare diseases ... no government can wriggle out of its core obligation of ensuring the right of access to health facilities for [the] vulnerable and marginalized section of society [such as] the petitioner by stating that it cannot afford to provide treatment for rare and chronic diseases.

Thus, by failing to adopt a policy for the provision of medicines for the treatment of rare diseases such as Gaucher's disease, the government had violated its constitutional obligation with regard to the right to health (Ibid paras 85-86). As health is a subject matter within the jurisdiction of the state government in India, the court ordered the Government of Delhi to 'discharge its constitutional obligation and provide the petitioner with enzyme replacement therapy ... free of charge as and when he requires it' (Ibid para 89).

The ruling of the court with regard to the non-derogable core obligation of the state to provide access to essential medicines at affordable prices, irrespective of resource constraints, has enormous implications for the tension between patent rights and the right to health in India. Even though the court in this case did not consider the tension between patent rights and the right to health, the court has confirmed by its ruling that the Indian government has a non-derogable core obligation to facilitate access to essential medicines at affordable prices.

This ruling implies that in any case where the exercise or enforcement of patent rights on pharmaceutical products granted by the government hinders poor patients from having access to essential medicines, there is a violation of the government's obligation to provide access to essential medicines at affordable prices. If this approach is incorporated into the decisions of the Indian courts whenever they are adjudicating disputes involving the interpretation or enforcement of patent rights, it will ensure that owners of patent rights on pharmaceutical products are not allowed to exercise their patent rights in a manner that impedes the enjoyment of the right to health.

Thus, three clear principles are discernible from the decisions of the Indian courts on the right to health. One, the state cannot justify its failure to provide medical facilities by arguing that it has limited financial resources. The state is obliged to at least adopt a policy with regard to the provision of medical facilities. Two, once a policy has been adopted by the state, the court will only interfere with such a policy if it is unconstitutional or unreasonable or arbitrary. As long as the policy itself is not unreasonable, the measures contained in the policy need not be adequate. Three, the state has a core obligation to provide access to essential medicines at affordable prices. There can be no derogation from this core obligation irrespective of financial constraints.

### **3. INCORPORATING THE RIGHT TO HEALTH INTO THE ADJUDICATION OF DISPUTES INVOLVING PHARMACEUTICAL PATENTS**

#### **3.1 Kenya**

In the 2008 case of *Pfizer Inc. v. Cosmos Limited*, Pfizer alleged that Cosmos had infringed its patent on a medicinal product known as 'azithromycin dihydrate' (*Pfizer Inc.*, 2008, p. 1).

Cosmos argued, *inter alia*, that it was entitled to import, manufacture, sell, and export the patented product without the authority of Pfizer by virtue of section 58(2) of the Industrial Property Act which allows parallel importation. Section 58(2) provides that ‘the rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya’. Cosmos presented evidence to the tribunal establishing that the medicines containing the patented product were available in Kenya having been imported from India, Bangladesh, and China (Ibid pp. 3-4). In other words, the patent rights of Pfizer, with respect to those products which were readily available in Kenya, had been exhausted. Cosmos was attempting to rely on the principle of international exhaustion of patent rights as reflected in section 58(2), and though this principle might not give Cosmos the right to manufacture the patented product, it would entitle Cosmos to import those patented products from India, Bangladesh, and China and to resell them in Kenya.

However, in a rather curious and confusing manner, the tribunal conflated parallel importation with compulsory licenses and voluntary licenses. According to the tribunal, ‘parallel importation ... is applicable for instance where the government has allowed a third party to exploit the patent, and that party imports the product from other countries where it is legitimately put on the market ... This could also be with the authority of the patent holder by way of a contractual or voluntary license’ (Ibid p. 13). The tribunal could not comprehend a situation where a third party could engage in the parallel importation of a patented product without the authorization of the patentee or the government and its definition of parallel importation clearly contradicts what is contained in section 58(2). Section 58(2) does not actually require a person or a company to obtain government authorization or a compulsory/voluntary license before engaging in parallel importation.

Cosmos equally argued that the patented product was used for the treatment of opportunistic infections in HIV/AIDS patients and that the WHO listed the product as an essential medicine for the treatment of genital chlamydia trachomatis and trachoma (Ibid p. 16). By raising this argument, Cosmos had highlighted a tension between the enforcement of Pfizer’s patent rights on one hand and the need to facilitate access to this essential medicine for Kenyan patients on the other hand. The resolution of this tension therefore required a proper appreciation of the fact that patent rights ought to serve the needs and interests of fundamental rights such as the right to have access to essential medicines at affordable prices. If the tension had been approached from this dimension, it would have enabled the tribunal to interpret the patent law with the objective of ensuring that it does not impede access to medicines. However, in this particular case, the Kenyan tribunal took the view that the product was not a first-line treatment for HIV/AIDS patients and that even if this were the case, it would not entitle the respondents to exploit the patent without authorization (Ibid p. 17).

By interpreting the provisions of section 58(2) in this manner and ignoring the impact this could have on access to anti-retroviral drugs in Kenya, the tribunal overlooked the rationale behind the introduction of parallel importation into the Kenyan Industrial Property Act of 2001 via the provisions of section 58(2). During the parliamentary debates on the 2001 Act, it was stated by the Kenyan Minister for Trade and Industry that the provision on parallel importation was specifically introduced to permit the importation into Kenya of ‘medicines which are required for human life, especially [for the treatment of] HIV/AIDS and [other]



opportunistic diseases, as well as malaria’ (Kenyan National Assembly Official Record 2001, p. 1043).

The tribunal thus failed to appreciate the essential distinction between the regulatory nature of patent rights and the fundamental nature of the right to have access to essential medicines. It could be argued that the tribunal failed to appreciate this essential distinction because Article 43(1)(a), which made the right to health a justiciable right in Kenya, was only introduced into the Kenyan Constitution in 2010 i.e. two years after the tribunal’s judgment. However, even without invoking a constitutional right to health, a tribunal that is mindful of the fundamental importance of securing access to medicines would have examined the rationale behind the inclusion of section 58(2) in the Kenyan patent law. As noted above, section 58(2) was introduced in order to facilitate the importation of medicines for the treatment of HIV/AIDS and opportunistic ailments. A tribunal that is mindful of the fundamental importance of facilitating access to affordable medicines would have construed section 58(2) in accordance with the objective of ensuring that the enforcement of a patent right does not defeat the aims of the drafters of the patent law.

In the more recent case of *Patricia Asero Ochieng et al. v. Attorney General*, the Kenyan High Court had an opportunity to consider the relationship between intellectual property rights and the right to health (*Patricia Asero Ochieng*, 2012). In this case, the petitioners were HIV/AIDS patients, and they alleged that certain sections of the Kenyan Anti-Counterfeit Act of 2008 threatened their access to essential drugs thereby infringing their right to life, dignity, and health (Ibid para 1). The petitioners argued that the government failed to specifically exempt generic drugs from the definition of counterfeit goods in the Act (Ibid para 14). Specifically, section 2 of the Act defined counterfeiting in relation to medicine to mean ‘the deliberate and fraudulent mislabelling of medicine with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging’. The respondents, however, argued that the Anti-Counterfeit Act was enacted to prohibit trade in counterfeit goods in Kenya and was not intended to prohibit generic drugs (Ibid para 39). The respondents argued that the Act was intended to ‘protect the public from the harm of using counterfeit goods and that extra care needs to be taken to ensure that the medicine in the market meets the required standard’ (Ibid para 42).

Contrary to the arguments of the respondents in this case, it appears that the real intent behind the Kenyan Anti-Counterfeit Act was not really the protection of the public from harm but the Act was designed to secure, among other things, the intellectual property rights of pharmaceutical companies. Von Braun and Munyi (2010, p. 243) point out that, because the two bills preceding the enactment of the Anti-Counterfeit Act were not backed by any public policy decision, it is ‘difficult to discern the real motive or motivations behind the enactment of the legislation’ but ‘during the legislative process, there was a lot of public debate, at least as demonstrated by numerous media reports on the effect counterfeiting has had on the local manufacturing sector’ and the ‘Kenya Association of Manufacturers ... was leading in the lobbying towards legislation on anti-counterfeiting’. Harrington and O’Hare (2014, p. 22) equally note that the Kenya Association of Manufacturers played a key role in securing the passage of the Act. According to Harrington and O’Hare (Ibid), the Kenya Association of Manufacturers ‘represents over 700 members, both domestic and foreign-owned firms, among whom are major pharmaceutical concerns marketing and manufacturing their products

in Kenya'. They note that the Association established an Anti-Counterfeit Committee and 'engaged closely in the legislative process itself' while also 'frequently briefing key parliamentary committees' (Ibid).

The former UN Special Rapporteur on the Right to Health, Anand Grover, filed an *amicus* brief in the *Ochieng* case. According to the former Special Rapporteur, 'the definition of "counterfeiting" within the Act effectively conflates generic medicines with medicines which are produced in violation of private intellectual property rights, and this conflation of legitimately produced generic medicines with those that possibly violate intellectual property rights is likely to have a serious adverse impact on the availability, affordability and accessibility of low-cost, high-quality medicines' (*Patricia Asero Ochieng*, para 35). Grover agreed with the contention of the petitioners that the Act could endanger the right to health because it does not exclude generic drugs (Ibid para 34). Grover also provided a definition of generic medicines (which was quoted in the court's judgment) as drugs that 'have the same composition and contain the same substances as patented formulations of the same drugs, and are essentially identical copies [that] can be used for the same purposes as their non-generic counterparts' (Ibid para 76).

In its analysis of the meaning and implication of the right to health, the High Court referred to Article 43(1)(a) of the Kenyan Constitution which guarantees the right to health, Article 12 of the ICESCR, and the UN CESCR's General Comment No. 14 on the right to health. The High Court proceeded to delineate the nature of the state's obligation with regard to the right to health. The court held that the state's obligation entails both a positive and a negative duty. The state has a positive duty to ensure that its citizens have access to health care services and medicines; it equally has a negative duty to refrain from taking actions that would affect access to these health care services and medicines (Ibid para 66). Thus, any legislative enactment that would make medicines too expensive for citizens would be in violation of the state's obligation (Ibid).

The court equally highlighted the danger inherent in conflating the definition of counterfeit drugs and generic drugs by referring to cases where generic drugs in transit were seized on the basis of being counterfeit (Ibid para 75). Though the court did not mention any particular country, it is obvious that the court was referring to instances like the seizure by Dutch Customs authorities in 2008 and 2009 of multiple shipments of drugs that were in-transit from India to developing countries in Africa and Latin America (Micara 2012). The court agreed with the petitioners and the Special Rapporteur that the 'definition of "counterfeit" in section 2 of the Act is likely to be read as including generic medication' and quoting from the Special Rapporteur's *amicus* brief, it stated that 'this would affect the availability of generic drugs and pose a real threat to the petitioners' right to life, dignity and health' (*Patricia Asero Ochieng*, para 78). The court disagreed with the respondent's argument that the Act was primarily intended to protect consumers from counterfeit medicines. According to the court 'the tenor and object of the Act is to protect the intellectual property rights of individuals' (Ibid para 82).

The court was of the view that the rights to life, dignity, and health must take priority over intellectual property rights. The court noted that if the Act is implemented as originally written, 'the danger that it poses to the right of the petitioners to access essential medicine ... is far greater and more critical than the protection of the intellectual property rights that the

Act seeks to protect. The right to life, dignity and health of the petitioners must take precedence over the intellectual property rights of patent holders' (Ibid para 85). The court thus adopted and applied the 'subjugation approach' by upholding the primacy of human rights over intellectual property rights. The High Court further held that, 'It is incumbent on the state to reconsider the provisions of section 2 of the Anti-Counterfeit Act alongside its constitutional obligation to ensure that its citizens have access to the highest attainable standard of health and make appropriate amendments to ensure that the rights of petitioners and others dependent on generic medicines are not put in jeopardy.' (Ibid para 88). However, unfortunately the Kenyan government failed to incorporate the court's ruling in this case into the recent amendments made to the Anti-Counterfeit Act in 2014 despite the demands of health activists in this regard. (Nzomo 2014).

Unlike the approach adopted by the tribunal in the *Pfizer v. Cosmos* case, the decision of the Kenyan High Court in this case demonstrates the court's recognition of the tension between the enforcement of intellectual property rights and the protection of the right to health. The court refused to be misguided into overlooking the fact that the Anti-Counterfeit Act was enacted to enhance the protection of intellectual property rights in Kenya. With the recognition that there was a tension to be resolved, the court equally demonstrated an implicit understanding of the essential distinction between the fundamental nature of the right to health and the regulatory nature of IPRs. This can be seen from the court's statement that the danger posed by the Anti-Counterfeit Act to the petitioner's right to access essential medicines was far greater and more critical than the protection of IPRs. It is therefore not surprising that the court, while not disparaging IPRs, held that the right to health must take priority over IPRs.

These two cases from Kenya illustrate the important role that courts can play in enhancing access to medicines in developing countries. In a situation where most courts adopt the approach of the tribunal in the *Pfizer* case, there is no doubt that patent rights will almost always trump the right to health. However, if courts adopt the more robust approach that was applied by the Kenyan High Court in the *Ochieng* case, it will lead to two things: one, states will be careful in implementing legislation (especially legislation on patent rights) that can significantly impede access to medicines; and, two, pharmaceutical companies that own patents on pharmaceutical products will ensure that they do not exercise their patent rights in ways that negatively affect the enjoyment of the right to health.

### **3.2 South Africa**

In *Pfizer Ltd. v. Cipla Medpro (Pty) Ltd.*, (*Pfizer*, 2005) Cipla Medpro had initiated revocation proceedings against Pfizer in 2004 with regards to one of Pfizer's pharmaceutical patents. Cipla had alleged that the patent was unclear and obvious. The patent in question concerned a 'besylate salt of amlodipine, a drug used for hypertension and reduction of blood pressure' (Ibid p. 2). Pfizer markets a product called Norvasc which contains the patented chemical while Cipla had already started to market its own generic version called Nortwin in South Africa even before Pfizer's patent expired or was revoked (Ibid). In response to Cipla's application for the revocation of its patent (which was set to expire in 2007), Pfizer brought this action for an interim interdict against Cipla to prevent the infringement of its patent pending the final determination of the revocation proceedings. In granting Pfizer's

application for an interim interdict, Botha J., sitting as the Commissioner of Patents, held that (Ibid p. 22):

If one looks at the broad picture: the respondents have hardly entered the market. The applicants have only two years of their patent left. In two years the respondents will be at liberty to sell Nortwin in any event. The applicant is a manufacturer that relies on patent protection to recoup the cost of research and development. The respondent is a manufacturer of generic products that are manufactured without the expense of original research. For that reason it is wrong to argue, as the respondents have done endlessly, that the applicants can retain their market share by reducing their prices. The regime of an open market is only something to which they have to submit on the expiry of the patent.

It is rather surprising that the only characters that featured in the court's 'broad picture' were just the applicant and the respondent – Pfizer and Cipla. The court appears to have been more concerned about the importance of ensuring that Pfizer is able to recoup the money it spent on research and development. While it is fair for pharmaceutical companies to seek to recoup their investment in producing new drugs, the approach adopted by the court completely ignores other important characters like poor patients who might not be able to afford to pay for Norvasc sold by Pfizer but who might be able to afford Nortwin sold by Cipla. In other words, the court should have considered the potential impact that Pfizer's patent rights could have on the enjoyment of the right to health by poor patients in South Africa.

In a latter case, *Aventis v. Cipla*, the dispute involved a patent for 'New Taxoid-Based Compositions' that belonged to Aventis and which covered claims for compositions containing 'Taxane' derivatives including the Taxane derivative known as 'docetaxel' (*Aventis*, 2011, para 2). Taxane derivatives such as docetaxel are used as chemotherapy treatments for a number of cancers (Ibid). Aventis was seeking an interim interdict against Cipla because, in March 2011, Aventis discovered that Cipla was about to import into South Africa two products made in India, 'Cipla Docetaxel' and 'Cipla Docetaxel solvent', which when mixed with the relevant product will constitute an infringement of the patent belonging to Aventis (Ibid para 3). Aventis therefore brought an application for an interdict to prohibit the respondents from mixing the Cipla products and an interdict to prohibit the respondents from selling the products to any person who will mix the products in accordance with the patent (Ibid para 3). The interim interdict was refused because the Commissioner of Patents was of the view that the applicants' prospect of success at a full trial was slender (Ibid para 26).

Aventis however appealed to the South African Supreme Court of Appeal and the decision of the Commissioner of Patents was overruled by the Supreme Court of Appeal (*Aventis*, 2012). With regard to Aventis' request for an interim interdict, the appellate court agreed with the arguments of the *amicus curiae*, Treatment Action Campaign that the public interest cannot be ignored when deciding whether or not to issue an interim interdict (Ibid para 46). The NGO based its opposition to the grant of an interim interdict on the right to health guaranteed in section 27(1) of the South African Constitution and urged the appellate court to construe the Patents Act 'through the prism of the Constitution' and in a way that appropriately balances the rights of a patentee against the constitutional rights of others (Ibid para 44).

The appellate court was however of the view that construing the Patents Act through the prism of the Constitution does not necessarily mean that Aventis should be denied the right to enforce its patent (Ibid para 45). In its consideration of the balance of convenience and the public interest, the court noted that there was no suggestion that Aventis was not able to meet the demand for the patented drug nor could it be said that Cipla's version of the drug offered superior medicinal benefits (Ibid para 55). The court further noted that there would be no material disruption to patients if an interdict was granted (Ibid). The court was not swayed by the argument that an interdict would adversely affect patients that could not afford Cipla's drug. According to the court, '[w]here the public is denied access to a generic [drug] during the lifetime of a patent, that is the ordinary consequence of patent protection and it applies as much in all cases. To refuse an interdict only so as to frustrate the patentee's lawful monopoly seems to ... be an abuse of the discretionary powers of a court' (Ibid para 56).

What can be deduced from this approach is that, while the court was willing to consider the public interest and the rights of patients, it was equally reluctant to allow these interests and rights to trump the monopoly rights of patentees. In essence, the court was willing to hold that the denial of access to generic drugs should be considered as part of the price the society pays for securing monopoly rights through the grant of patents. The court did not however attempt to consider whether the right to health could take precedence over patent rights in certain cases. This is probably because it was unnecessary to do so in this particular case. Based on the facts presented before the court, there would be no material prejudice to poor patients if an interim interdict was granted to Aventis. It was established before the court that Aventis was already marketing its own generic version of the patented drug and, more importantly, the patented drug itself was already being sold to the government at a rate which was cheaper than the price of Cipla's generic version (Ibid para 57). The court therefore held that Aventis' patented drug was 'considerably more accessible' to patients dependent on public health care than Cipla's generic version and that 'there will be no prejudice at all to those patients, or to the state, if an interdict were to be granted' (Ibid para 58).

### **3.3 India**

In the case of *Hoffmann-La Roche Ltd. v. Cipla Ltd.*, the Delhi High Court refused to grant an injunction sought by Roche against Cipla for the latter's production of 'Erloticip' (a generic version of Roche's patented anti-cancer drug known as 'Erlotinib'). The Delhi High Court noted that (*Hoffmann-La Roche*, 2008, para 85):

[T]he Court cannot be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted ... The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if [an] injunction [were to be] granted ... Another way of viewing it is that if the injunction in the case of a life saving drug were to be granted, the Court would in effect be stifling Article 21 [of the Indian Constitution] so far as those [who] would have or could have access to Erloticip are concerned.

According to the Delhi High Court, 'as between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for people to a life saving drug, the balance has to be tilted in favour of the latter' (Ibid para 86). The court observed

that the damage that would be suffered by Roche (the patent owner) in this case can be assessed in monetary terms but the ‘injury to the public which would be deprived of the defendants product, which may lead to shortening of lives of several unknown persons, who are not parties to the suit, and which damage cannot be restituted in monetary terms, is not only uncompensatable, it is irreparable’ (Ibid).

The decision of the Delhi High Court in this case was upheld on appeal by the Division Bench of the Delhi High Court (*Hoffmann-La Roche*, 2009). In concurring with the trial court, the Division Bench (Ibid para 81) held that,

[I]n a country like India where [the] question of general public access to life saving drugs assumes great significance, the adverse impact on such access which the grant of [an] injunction in a case like the instant one is likely to have, would have to be accounted for. [Erloticip] is the Indian equivalent produced by the defendant in India as a generic drug manufacturer. It is priced at Rs. 1600 per tablet. Even if this does not make it inexpensive, the question of [the] greater availability of such [a] drug in the market assumes significance.

However, the Delhi High Court has also held in *Novartis v. Cipla Ltd* that a generic drug company cannot rely on the right to life contained in Article 21 of the Indian Constitution to justify the infringement of a valid patent (*Novartis*, 2015, para 89). In this case, the court granted an injunction restraining Cipla from infringing Novartis’ patent on Indacaterol (a drug used in the treatment of chronic obstructive pulmonary disease). The court stated that Novartis had established a prima facie case for the validity of its patent and that Cipla has merely urged grounds of invalidity by relying on documents which according to Cipla constitutes prior art ‘without explaining to the court and to the other side ... how these documents can be categorized as [prior art]’ (Ibid para 83). The court further stated that Novartis, on the other hand, provided the points of distinction between the earlier patents relied upon as prior art and its own patent (Ibid). The court held that, ‘if [a] patent is valid, the defendant has failed to establish [a] prima facie credible defence and the case of infringement is made out by the patentee, the patentee may be entitled [to an] injunction’ (Ibid para 87).

The court distinguished this case from that of *Hoffmann-La Roche Ltd. v. Cipla Ltd* where a credible challenge was raised to the validity of Roche’s patent by Cipla and it stated that ‘Article 21 cannot be pressed into service by an infringer seeking to justify the infringement of a valid patent and the statutory rights conferred by the statute’ (Ibid paras 74, 89). The court further stated that if Cipla was ‘so very much concerned about the welfare of [the] public ... and its grounds are genuine and correct, it could have filed [an] application for [the] grant of [a] Compulsory Licence’ (Ibid para 91). The implication of the court’s ruling in this case is that a generic drug company cannot rely on the right to health to justify the infringement of a valid pharmaceutical patent. If a generic drug company believes that the demand for a patented drug is not being met by the patentee or that the patentee is selling its drug at a price that is not reasonably affordable, the generic company can apply for a compulsory licence.

The case of *Natco v. Bayer* is the first case in India in the post-TRIPS Agreement era where an applicant invoked the relevant provisions of the Indian Patents Act to seek the grant of a compulsory licence (*Natco*, 2012). The patentee in this case, Bayer, invented a drug called

‘Sorafenib’ and obtained an Indian patent for the drug in 2008. The drug is sold under the trade name ‘Nexavar’ and it is used for the treatment of kidney cancer and liver cancer. The applicant, Natco, an Indian generic drug manufacturer, had initially requested for a voluntary licence from Bayer to sell the drug at a cheaper price. Bayer did not grant this request and Natco subsequently applied for a compulsory licence. In granting Natco’s request for a compulsory licence, one of the issues considered by the Indian Controller of Patents was the price at which the drug was being sold in India. According to section 84(1)(b) of the Indian Patents Act of 2005, one of the grounds for the grant of a compulsory licence is that ‘the patented invention is not available to the public at a reasonably affordable price’.

Natco argued that the price of the drug was ‘too high and simply unaffordable by the common man making the product inaccessible and out of reach’ (Ibid para 11). According to Natco, a drug that costs Rs. 2,80,000 per month ‘will push a large proportion of the population into poverty’ (Ibid). In response, Bayer argued, *inter alia*, that ‘reasonable’ price must mean ‘reasonable’ to the public and the patentee as well, and that ‘the cost of R&D and the cost of manufacture, both have to be taken into account while determining “reasonable affordable price”’ (Ibid).

In deciding to grant the compulsory licence, the Controller agreed that the drug, being sold at a price of Rs. 2,80,000 per month, was not reasonably affordable to members of the public (Ibid). The Controller disagreed with Bayer’s argument that ‘reasonable affordable price’ should be construed with reference to both the public and the patentee, and held that it has to be construed predominantly with reference to the public (Ibid). According to the terms of the compulsory licence granted to Natco by the Controller, Natco is meant to sell the drug at the price of Rs. 8880 per month (Ibid para 15).

Bayer subsequently lodged an appeal against the decision of the Controller at the Indian Intellectual Property Appellate Board (IPAB). In March 2013, IPAB issued its final judgment and it dismissed Bayer’s appeal against the grant of the compulsory licence (Bayer, 2013). IPAB upheld the order of the Controller of Patents though it increased the rate of royalty to be paid by Natco to Bayer from 6% to 7% (Ibid para 54). In its final judgment, IPAB referred to section 83 of the Indian Patents Act which contains the general principles applicable to the working of patented inventions in India. Specifically, section 83(d) provides that patents should not impede the protection of public health. Section 83(g) further states that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public. IPAB noted that it could not ‘ignore these markers’ in its decision (Ibid para 22).

IPAB’s final decision in this case indicates that it was mindful of the need to protect the right to health and the right to have access to medicines. In its judgment, reference was made to the Doha Declaration on the TRIPS Agreement and Public Health of 2001 (World Trade Organization Ministerial Declaration 2001). The Doha Declaration provides, *inter alia*, that the TRIPS Agreement ‘does not and should not prevent members from taking measures to protect public health ... [and] that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all’ (Ibid para 4). Importantly, IPAB noted that, under the Doha Declaration, countries ‘affirmed their full right to use the TRIPS flexibilities ... especially in connection with [their] right to protect public health and in particular, to

promote access to medicines for all’ (*Bayer*, 2013, para 20). This led IPAB to the conclusion that the running theme is ‘public health and access to medicine, a facet of [the] right to life’ (*Ibid*). IPAB’s statement, that public health and access to medicine is a facet of the right to life, definitely implies an awareness on the part of IPAB that it was dealing with a matter that involved the right to health.

IPAB further held that ‘the Controller was right in holding that the sales of the drug by the appellant at the price of about [Rs.] 280,000 ... considering the purchasing capacity of the public ... was not reasonably affordable to the public’ (*Ibid* para 44). IPAB’s decision was affirmed by the Bombay High Court in July 2014 (*Bayer*, Bombay High Court 2014) and Bayer’s subsequent petition to the Indian Supreme Court for a special leave to appeal against the judgment of the Bombay High Court was dismissed by the Supreme Court in December 2014 (*Bayer*, Supreme Court of India 2014).

## CONCLUSION

This chapter has shown that the courts in Kenya, South Africa, and India have interpreted the right to health to include an obligation on the state to provide/facilitate access to medicines. By incorporating the right to health into the adjudication of patent disputes, national courts in developing countries can play a crucial role in improving access to medicines at affordable prices. The incorporation of the right to health into the adjudication of disputes involving pharmaceutical patents does not necessarily imply that patent rights will no longer be recognized and respected, it only means that courts should not permit patent rights to be exercised and enforced in a manner that impedes access to medicines and the enjoyment of the right to health.

## REFERENCES

1. *Aventis v. Cipla*. (2011, October 20). Unreported Case No.: P93/8936, decision of the Court of the Commissioner of Patents for the Republic of South Africa.
2. *Aventis v. Cipla*. (2012, July 26). Case Nos.: 139/2012 & 138/2012; [2012] ZASCA 108, decision of the South African Supreme Court of Appeal.
3. *Bayer v. Union of India and others*. (2013, March 4). OA/35/2012/PT/MUM, decision of the Indian Intellectual Property Appellate Board.
4. *Bayer v. Union of India and others*. (2014, July 15). Writ Petition No. 1323 of 2013, decision of the Bombay High Court.



5. *Bayer v. Union of India and others*. (2014, December 12). Petition(s) for Special Leave to Appeal (C) NO(S). 30145/2014, decision of the Supreme Court of India.
6. Chapman, A. (2001). Approaching intellectual property as a human right: Obligations related to article 15(1)(c). *Copyright Bulletin*, 35(3), 4-36.
7. *Confederation of Ex-Servicemen Associations and others v. Union of India and others*. (2006, August 22). Writ Petition (civil) 210 of 1999, decision of the Indian Supreme Court.
8. *Consumer Education & Research Centre and others. v. Union of India and others*. (1995, January 27). 1995 SCC (3) 42, decision of the Indian Supreme Court.
9. Correa, C., & Matthews D. (2011). The Doha Declaration ten years on and its impact on access to medicines and the right to health. Discussion paper. United Nations Development Programme.  
[http://www.undp.org/content/dam/undp/library/hiv/aids/Discussion\\_Paper\\_Doha\\_Declaration\\_Public\\_Health.pdf](http://www.undp.org/content/dam/undp/library/hiv/aids/Discussion_Paper_Doha_Declaration_Public_Health.pdf). Accessed 23 January 2015.
10. Dhanda, A. (2013). Realising the right to health through co-operative judicial review: An analysis of the role of the Indian Supreme Court. In O. Vilhena, U. Baxi, & F. Viljoen (eds.), *Transformative constitutionalism: Comparing the apex courts of Brazil, India and South Africa* (pp. 405-413). Pretoria University Law Press.
11. Drahoš, P. (1998). The universality of intellectual property rights: Origin and development. In: Intellectual property and human rights. Proceedings of a panel discussion held by the World Intellectual Property Organization in collaboration with the Office of the UN High Commissioner for Human Rights, World Intellectual Property Organization, Geneva, 9 November 1998.
12. Drahoš, P. (1999). Intellectual property and human rights. *Intellectual Property Quarterly*, 3, 349-371.
13. Ferraz, O.L.M. (2013). Between usurpation and abdication? The right to health in the courts of Brazil and South Africa. In O. Vilhena, U. Baxi, & F. Viljoen (eds.),

*Transformative constitutionalism: Comparing the apex courts of Brazil, India and South Africa* (pp. 375-404). Pretoria University Law Press.

14. Ghosh, S. (2008). When property is something else: Understanding intellectual property through the lens of regulatory justice. In A. Gosseries, A. Marciano, & A. Strödel (eds.), *Intellectual property and theories of justice* (pp. 106-121). Palgrave Macmillan.
15. Gold, E. R. (2013). Patents and human rights: A heterodox analysis. *The Journal of Law, Medicine and Ethics*, 41(1), 185-198.
16. Groscheide, W. (ed.). (2010). *Intellectual property and human rights: A paradox*. Edward Elgar Publishing.
17. Harrington, J., & O'Hare, A. (2014). Framing the national interest: Debating intellectual property and access to essential medicines in Kenya. *The Journal of World Intellectual Property*, 17(1-2), 16-33 (2014). doi: 10.1002/jwip.12020.
18. Helfer, L. (2003). Human rights and intellectual property: Conflict or coexistence? *Minnesota Intellectual Property Review*, 5(1), 47-61.
19. Helfer, L., & Austin, G. (2011). *Human rights and intellectual property: Mapping the global interface*. New York: Cambridge University Press.
20. *Hoffmann-La Roche v. Cipla Ltd.* (2008, March 19). I.A. 642/2008 in CS(OS) 89/2008, decision of the High Court of Delhi.
21. *Hoffmann-La Roche v. Cipla Ltd.* (2009, April 24). FAO (OS) 188/2008, decision of the Division Bench of the High Court of Delhi).
22. Hristova, M. (2011). Are intellectual property rights human rights? Patent protection and the right to health. *Journal of the Patent and Trademark Office Society*, 93(3), 339-361.
23. International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), (1996).

24. Kenyan National Assembly Official Record (Hansard). (2001, June 12).
  
25. Marks S. (2009). Access to essential medicines as a component of the right to health. In A. Clapham & M. Robinson (eds.), *Realizing the right to health*, Swiss human rights book series, vol 3 (pp. 80-99). Zurich: Ruffer & Rub.
  
26. Micara, A.G. (2012). TRIPS-plus border measures and access to medicines. *The Journal of World Intellectual Property*, 15(1), 73-101 (2012). doi: 10.1111/j.1747-1796.2011.00431.x.
  
27. Millum, J. (2008). Are Pharmaceutical patents protected by human rights? *Journal of Medical Ethics*, 34, e25 (2008). doi: 10.1136/jme.2007.022483.
  
28. *Minister of Health v. New Clicks*. (2005, September 30). CCT 59/2004, decision of the South African Constitutional Court.
  
29. *Minister of Health v. Treatment Action Campaign (No.2)*. (2002, July 5). CCT 8/02, decision of the South African Constitutional Court.
  
30. *Mohd. Ahmed (Minor) v. Union of India and others*. (2014, April 17). W.P.(C) 7279/2013, decision of the High Court of Delhi.
  
31. *Natco v. Bayer*. (2012, March 9). Compulsory Licence Application No. 1 of 2011, decision of the Indian Controller of Patents.
  
32. *Novartis v. Cipla Ltd*. (2015, January 9). I.A. No. 24863/2014 in CS(OS) 3812/2014, decision of the High Court of Delhi.
  
33. Nzomo, V. (2014). President assents to Anti-Counterfeit (Amendment) Act 2014. IP Kenya. <https://ipkenya.wordpress.com/2014/12/17/president-assents-to-anti-counterfeit-amendment-act-2014/>. Accessed 24 January 2015.
  
34. *Paschim Banga Khet Samity v. State of West Bengal*. (1996, May 6). (1996) 4 SCC 37, decision of the Indian Supreme Court.

35. *Patricia Asero Ochieng et al. v. Attorney General*. (2012, April 20). Petition No. 409 of 2009, decision of the Kenyan High Court.
  
36. *Pfizer Ltd. v. Cipla Medpro (Pty) Ltd.* (2005, March 24). Case No.: 87/2439, (2005) BIP 1; [2005] ZACCP 1, decision of the Court of the Commissioner of Patents for the Republic of South Africa.
  
37. *Pfizer Inc. v. Cosmos Limited*. (2008, April 25). Case No. 49 of 2006, decision of the Kenyan Industrial Property Tribunal at Nairobi.
  
38. Plomer, A. (2013). The human rights paradox: Intellectual property rights and rights of access to science. *Human Rights Quarterly*, 35(1), 143-175.
  
39. *Re Certification of the Constitution of the Republic of South Africa, 1996*. (1996, September 6). Case CCT 23/96, decision of the South African Constitutional Court.
  
40. Sell, S.K. (2007). TRIPS-Plus free trade agreements and access to medicines. *Liverpool Law Review*, 28(1), 41-75 (2007). doi: 10.1007/s10991-007-9011-8.
  
41. *Soobramoney v. Minister of Health*. (1997, November 27). Case CCT 32/97, decision of the South African Constitutional Court.
  
42. *State of Punjab v. Ram Lubhaya Bagga*. (1998, February 26). (1998) 4 SCC 117, decision of the Indian Supreme Court.
  
43. Torremans, P. (ed). (2008). *Intellectual property and human rights*. Kluwer Law International.
  
44. United Nations Committee on Economic, Social and Cultural Rights. (2000). General Comment No. 14 on the right to the highest attainable standard of health, article 12 of the International Covenant on Economic, Social and Cultural Rights. U.N. Doc. E/C.12/2000/4.

45. United Nations Committee on Economic, Social and Cultural Rights. (2005). General Comment No. 17 on the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author, article 15(1)(c) of the International Covenant on Economic, Social and Cultural Rights. U.N. Doc. E/C.12/GC/17.
46. United Nations Human Rights Council. (2013). Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. A/HRC/23/L.10/Rev.1.
47. Universal Declaration of Human Rights, G.A. Res. 217A (III), (1948).
48. Von Braun, J., & Munyi, P. (2010). New enforcement mechanisms challenge the legality of generics in the name of public health: The emergence of anti-counterfeiting legislation in East Africa. *African Journal of International and Comparative Law*, 18(2), 238-253.
49. World Health Organization. (2015). Essential medicines. [http://www.who.int/topics/essential\\_medicines/en/](http://www.who.int/topics/essential_medicines/en/). Accessed 22 January 2015.
50. World Trade Organization Ministerial Conference. (2011, November 14). Declaration on the TRIPS Agreement and public health. WT/MIN(01)/DEC/2.
51. Yu, P.K. (2007a). Reconceptualizing intellectual property interests in a human rights framework. *U. C. Davis Law Review*, 40(3), 1039-1149.
52. Yu, P.K. (2007b). Ten common questions about intellectual property and human rights. *Georgia State University Law Review* 23(4), 709-753.